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EXAMINER	
BHAT, NARAYAN KAMESHWAR	
ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/579,674	DUTRECQ ET AL.	
	Examiner	Art Unit	
	NARAYAN K. BHAT	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-17* is/are pending in the application.

4a) Of the above claim(s) *9-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This office action is written in reply to applicant's correspondence filed February 6, 2008. Claims 1 and 4 were amended and claim 8 was cancelled. Applicant's amendments requiring deep tissue samples and drying the samples retained on the means for abrasive sampling necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

2. Claims 1-7 and 9-17 are pending in this application.

3. Claims 9-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 9, 2007.

4. Claims 1-7are under prosecution

Amendments to Claims

5. Amendments to the claims 1 and 4 have been reviewed and entered.

35 USC § 112 Sixth Paragraph

6. The following is a quotation of the sixth paragraph of 35 U.S.C. 112:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

7. The limitation of "means for abrasive sampling" in claim 1, line 4 is not being treated under 35 USC 112, sixth paragraph because the claim itself recites sufficient

structure for performing specified function (see claim 1, lines 5-6). Therefore, "means for abrasive sampling" do not meet the three-prong analysis for examination under 112 Sixth paragraph (See MPEP 2181-R6).

8. The limitation of "means for abrasive sampling" in claim 4, line 3 is not being treated under 35 USC 112, sixth paragraph because the claim itself recites sufficient structure for performing specified function (see claim 1, lines 5-6). Therefore, "means for abrasive sampling" do not meet the three-prong analysis for examination under 112 Sixth paragraph. Therefore claims 1 and 4 are not examined under 112 sixth paragraph analysis.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (USPGPUB NO. 2002/0164272 published Nov. 7, 2002) in view of Chisum (USPN 5,780,305 issued Jul. 14, 1998) and further in view of Volossiouk et al (Applied and Environmental Microbiology, 1995, 61, 3972-3976).

Regarding claim 1, Harris teaches a method for collecting sample for nucleic acid analysis that includes a sampling device with a cutting edge (Fig. 8, # 150, paragraph 0040) for collecting a tubular samples from a sample source (Fig. 8, sample source # 70, paragraph 0040). Harris further teaches applying pressure on the surface of the sample (Fig. 8, sample surface # 80, paragraph 0040) and penetrating inside of the sample source (Fig. 8, paragraph 0040) to force the sample inside the chamber of the sampling device (Fig. 8, sample -# 40, chamber # 160, paragraphs 0006-0007, 0040 and 0044). The sampling device of Harris is the abrasive sampling means, because sampling device cutting edge comprises a solid material made of steel, i.e., metal (Fig. 8, # 150). Furthermore, sampling device penetrates into the biological material by pressure and produces incision into the sample via cutting and retains the sample in the device, which is defined also as the means for abrasive sampling in the instant specification as (Instant specification, USPGPUB, paragraph 0018).

Harris also teaches that the sample comprises plant, wood, paper, cloth, tissues and is for DNA analysis (paragraphs 0002 and 0007), thus teaching sample is a biological material of plant origin in the form of cells. It is noted that Harris teaches

collecting samples for DNA analysis, implying that the biological material contains DNA. It is known in the art the cells contain DNA and therefore sample collected by Harris by abrasive sampling means is capable of retaining biological material in the form of cells. Harris also teaches that samples are collected by penetrating into the sample surface, i.e., below the surface of the sample and cutting the samples in a tubular form (Fig. 8, paragraphs 0007, 0040 and 0044), which is a 'deep tissue sample' as defined in the instant specification (See instant specification, Fig. 4, USPGPUB, paragraph 0075).

Harris further teaches the expulsion of tubular sample into the receptacle (Fig. 9, sample # 40, receptacle # 90, paragraphs 0041 and 0043) and is silent about the surrounding environment. Harris also teaches the samples are used for DNA analysis (paragraph 0002).

As described above, Harris is silent about drying the samples retained in the sampling device. However, sample drying was known in the art before the claimed invention was made, as taught by Chisum, who teaches methods for collecting and drying samples (column 3, lines 13-18). Chisum further teaches that samples on the sampling head (Fig, 3, # 320), is covered with a shield (Fig, 3, # 300) having opening (Fig. 3, # 310) for drying the sample (Example 3, column 9, lines 30-67). Chisum also teaches that drying samples prevents microbial contamination (column 5, lines 17-24) and sample degradation (column 8, lines 1-8).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the sampling method of Harris and include the drying step of Chisum.

One having the ordinary skill in the art would be motivated to modify the sampling method of Harris and include the drying step of Chisum with a reasonable expectation of success with the expected benefit of preventing microbial contamination and sample degradation (column 5, lines 17-24, column 8, lines 1-8), thus preserving the sample for long time in the method of Harris.

Harris and Chisum are silent about steps of isolating nucleic acid from cells and assaying nucleic acids by molecular hybridization. However, steps of isolating nucleic acid from cells and assaying by molecular hybridization were known in the art before the claimed invention was made as taught by Volossiouk et al.

Regarding claim 2, Harris teaches the expulsion of tubular sample in to the receptacle (Fig. 9, sample # 40, receptacle # 90, paragraphs 0041 and 0043) and is silent about the surrounding environment. Chisum teaches that sampling of biological material is done in the surrounding air to dry the sample (Chisum, column 6, lines 46-57).

Regarding claim 3, Harris teaches a method for collecting biological samples wherein the sampling device is provided as kit for collecting samples and transporting the sample (paragraphs 0006 and 0009), thus teaching sampling is done outside of a laboratory where the assaying will be done and further comprising transporting the abrasive sampling means loaded with their respective samples of biological material to said laboratory.

Volossiouk et al teaches isolating nucleic acids from the cells (Fig. 1, pg. 3973, column 2, paragraph 3) and assaying the nucleic acids by PCR, which requires

molecular hybridization with primer and sample (Fig. 2, pg. 3973, column 1 and 2, paragraph 2 and 3).

Regarding claim 6, Volossiouk teaches a method wherein the assaying by molecular hybridization is done by polymerase chain reaction (PCR) (Fig. 1, last step, pg. 3973 column 1, paragraphs 2 and 3).

Regarding claim 7, Volossiouk teaches a method that includes determining the presence of a verticillium wilt pathogenic agent in the biological material by PCR, i.e., a molecular hybridization (pg. 3972 column 2, paragraph 2).

Volossiouk et al also teaches that isolation and detection of nucleic acids by molecular hybridization from sample is very simple and allows monitoring the pathogens and indicator bacteria in the economically important plants rapidly and in a cost efficient manner (Abstract, pg. 3972, column 1, paragraph 1, column 2, paragraph 2).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the nucleic acid assay method of Harris and Chisum and include the nucleic acid isolation and detection steps of Volossiouk et al.

One having the ordinary skill in the art would be motivated to modify the nucleic acid assay method of Harris and Chisum and include the nucleic acid isolation and detection steps of Volossiouk et al with a reasonable expectation of success with the expected benefit of monitoring the pathogens and indicator bacteria in the economically important plants rapidly and in a cost efficient manner as taught by Volossiouk et al (Abstract, pg. 3972, column 1, paragraph 1, column 2, paragraph 2).

12. Claims 1, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (USPGPUB NO. 2002/0164272 published Nov. 7, 2002) and Chisum (USPN 5,780,305 issued Jul. 14, 1998) and Volossiouk et al (Applied and Environmental Microbiology, 1995, 61, 3972-3976) as applied to claim 1 above and further in view of Fenrich et al (USPGPUB NO. US 2004/01219537 filed May 2, 2003).

The claim 5 is dependent from claim 4, which is dependent from claim 1. Teachings of Harris, Chisum and Volossiouk et al regarding claim 1 are described previously in this office action.

Regarding claim 4, Harris teaches collecting samples using the sampling device, i.e., means for abrasive sampling, loaded with their respective samples (Fig. 8, sample source # 70, sample chamber # 160, sample # 40, paragraph 0040). Harris also teaches samples are used for DNA analysis (paragraph 0002). Harris and Chisum are silent about immersing the sampling means into an extraction buffer.

Volossiouk et al teaches a method that include extraction of the nucleic acids, comprising the steps of mixing the abrasive sampling means loaded with their respective samples of biological material into an extraction buffer (Fig. 1, step 5) and agitating the extraction buffer, separating the nucleic acids, and recovering clarified solution containing the nucleic acids (Fig. 1, steps 6-8, pg. 3973, column 1, paragraph 1).

Regarding claim 5, Volossiouk et al teaches a method of nucleic acid extraction wherein the separations step consists of a centrifugation, and the supernatant constitutes the clarified solution (pg. 3973, column 1, paragraph 1).

Harris, Chisum and Volossiouk et al are silent about immersing the sampling means into an extraction buffer. However immersing the abrasive sampling means loaded with their respective sample of biological material in to an extraction buffer was known in the art before the claimed invention was made as taught by Fenrich et al , who teaches a method to collect samples using an abrasive surface and further teaches isolating DNA from the cells adhered to the abrasive surface and collecting the DNA for further analysis, thus teaching immersing the abrasive sampling means loaded with their respective samples of biological material into an extraction buffer (paragraph 0056).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the nucleic acid assay method of Harris, Chisum and Volossiouk et al and include the step of immersing the cells on the abrasive surface in to the extraction buffer of the method of Fenrich et al.

One having the ordinary skill in the art would be motivated to modify the nucleic acid assay method of Harris, Chisum and Volossiouk et al with a reasonable expectation of success with the expected benefit of collecting DNA from all of the precious biological samples from abrasive means as taught by Fenrich et al (paragraph 0056), thus providing more cells in the nucleic acid isolation method of Harris, Chisum and Volossiouk et al to collect higher amounts of nucleic acids.

Response to Remarks from Applicants

Claim rejections under 35 U.S.C. § 102(b) and 102(e)

13. Applicant's arguments with respect to claims 1-2 and 6-8 as anticipated by Volossiouk et al have been considered but are moot in view of the new ground(s) of rejection necessitated by claim amendments (Remarks, pgs. 4-5).

Applicant's arguments with respect to claims 1-4 and 6 as anticipated by Fenrich et al have been considered but are moot in view of the new ground(s) of rejection necessitated by claim amendments (Remarks, pgs. 5-6).

Claim Rejections under 35 U.S.C. § 103(a)

14. Applicant's arguments with respect to claims 1 and 3-5 have been considered but are moot in view of the new ground(s) of rejection necessitated by claim amendments (Remarks, pgs. 7-8).

Conclusion

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action

is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Narayan K. Bhat/

Examiner, Art Unit 1634

Narayan K. Bhat, Ph. D.

/BJ Forman/

Primary Examiner, Art Unit 1634